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PATENT HAPPENINGS

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on judicial, legislative, and administrative developments in patent law.

HIGHLIGHTS

JUDICIAL HAPPENINGS

Prosecution History Estoppel

In another installment in the *Festo* saga, a panel of the Federal Circuit held that alternative structure alleged to be an equivalent of a narrowed claim limitation is "foreseeable," and therefore excluded from the permissible scope of equivalents for that claim limitation, if the alternative structure was in the prior art at the time the applicant amended its claim, even if at that time one of skill in the art would not recognize or appreciate that the alternative structure could serve as an equivalent. *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, No. 05-1492, 2007 WL 1932269 (Fed. Cir. July 5, 2007) (*Festo XIII*) (Dyk, Michel and Newman). The opinion addresses the unusual circumstance where subject matter asserted to be an equivalent was known to be capable for use as a substitute for a claim element at the time of infringement but was not so known at the time the patent applicant made its narrowing amendment that caused the literal scope of the amended claim not to cover the subject matter. Current jurisprudence requires that a fact finder must determine whether alternative subject matter is an equivalent of a claim element based on the knowledge existing at the time of the infringement. *Warner-Jenkinson Co. Inc. v. Hilton Davis Chemical Co.*, 520 U.S. 17, 37 (1997). But in the context of evaluating whether the presumption of total surrender from a narrowing amendment can be rebutted, current jurisprudence requires determining whether alternative subject matter is "foreseeable" based on the knowledge existing at the time the applicant made its narrowing amendment. *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 738 (2002) (*Festo VIII*) (a patentee can rebut the presumption of surrender by showing that the alleged equivalent would have been "unforeseeable *at the time of the amendment* and thus beyond a fair interpretation of what was surrendered") (emphasis added).

In *Festo XIII*, the court took the position that after-arising knowledge of equivalence will not save a patentee that surrendered known subject matter by a narrowing amendment, even if the patentee had no reason to know it was surrendering equivalent subject matter. Thus, Judge Dyk stated: "An equivalent is foreseeable if one skilled in the art would have known that the alternative existed in the field of art as defined by the original claim scope, even if the suitability of the alternative for the particular purposes defined by the amended claim scope were unknown." *Festo XIII*

at *10. In reaching this holding, the panel rejected the patentee's proposed test that the equivalent had to be "*foreseeable* to a person of ordinary skill in the art *to accomplish the claimed invention*, i.e., perform the same function in substantially the same way to achieve the same result, looking only at the information available at the time of the amendment." The panel held that the standard was not foreseeability of use in the claimed invention, as set forth by the amended claim, but foreseeability of use within the original claim scope. The panel also rejected the notion that the tests for determining factual equivalency (function-way-result or insubstantiality of the differences) should apply in determining foreseeability. Instead, the panel held that "an alternative is foreseeable if it is disclosed in the pertinent prior art in the field of the invention" and without "requir[ing] the knowledge that the equivalent would satisfy the function-way-result test or the insubstantial differences test." *Id.* at *7-*10. To address the Supreme Court's instruction that excluded subject matter should be "a fair interpretation of what was surrendered," the panel held that it was not unfair to find a surrender of subject that a "reasonable applicant at the time of the amendment would have been aware of the equivalent as an alternative under the broader claim before the amendment." *Id.* at *9.

Applying its new test, the panel affirmed the district court's ruling that the use of an aluminum sleeve was a foreseeable alteration of the claimed invention. According to the panel, since the pertinent prior-art disclosed the use of non-magnetic sleeves at the time the patentee amended its claim, the patentee "could have claimed use of a non-magnetizable sleeve but did not do so." Consequently, in the panel's view the patentee had surrendered all non-magnetizable sleeves when it made its narrowing amendment that claimed the sleeve be made of a magnetizable material. This surrender applied to aluminum sleeves, even though at that time of the amendment non-magnetic aluminum was not known to function like a magnetizable sleeve. *Id.* at *11

Characterizing the panel's decision as "stray[ing] from controlling precedent as well as from logic," Judge Newman dissented. She noted that "[h]indsight is not foreseeability[,]" and therefore stated her view that "if the particular technology is not recognized as equivalent at the time of the application . . . that technology cannot be foreseeable." She further noted that the panel's ruling effectively revived the "absolute bar" rule the Supreme Court rejected when it considered the case in 2002. *Id.* at *12-*14.

Claim Construction

In a second case decided this year by the Federal Circuit involving an infringement dispute between Honeywell and Universal Avionics regarding Honeywell's patent on a terrain warning system for aircrafts, the Federal Circuit, in *Honeywell Int'l, Inc. v. Universal Avionics Sys. Corp.*, No. 2006-1406, 2007 WL 1892472 (Fed. Cir. July 3, 2007) (Bryson, Gajarsa and Plager), affirmed the claim constructions rendered by the district court, and affirmed a jury verdict finding infringement. The accused infringer had challenged the correctness of three of the district court's claim constructions. The first disputed construction concerned a claim limitation reciting "the *heading* of the aircraft," and whether the inventor acted as his own lexicographer to define the term "heading" in a manner contrary to its normal usage. Agreeing with the district court, the Federal Circuit held that the specification and prosecution history showed that the inventor had indeed used the term "heading" in the manner contrary to its normal usage and that this contrary usage would control even though the inventor's lexicographic definition arose only by implication. The court noted that if the customary meaning of the term "heading" was applied, one of the preferred embodiments of the invention that the inventor had characterized as being an important feature of the invention would not fall within the scope of the claim, and found this persuasive evidence to apply the contrary meaning. *Id.* at *2-*5.

Judge Plager dissented from this aspect of the ruling. Noting the policy reason for why courts should not rewrite patent claims to cure drafting errors he stated: "[I]t is not the province of the courts to salvage poorly—or incorrectly—drafted patent claims. Fair notice to the public, and to competitors, of what is claimed depends on our holding patentees to what they claim, not to what they might have claimed. It is the responsibility of those who seek the benefits of the patent system to draft claims that are clear and understandable. When courts fail to enforce that responsibility in a meaningful way they inevitably contribute an additional element of indeterminacy to the system. Sometimes being kind to a party results in being unkind to the larger interests of the society." *Id.* at *9.

For the second claim construction dispute, the Federal Circuit rejected the accused infringer's argument that the prosecution history showed that the

patentee had disclaimed distance from the airport as being a parameter to use in the warning system. The panel noted that while the prosecution history could be read in a way that supported the accused infringer's disclaimer argument justifying a narrow construction, the history could also be read in a manner that supported the patentee's broader construction. Because of this ambiguity, the court held that the prosecution history did "not constitute a sufficiently clear and deliberate statement to meet the high standard for finding a disclaimer of claim scope." *Id.* at *6.

As to the third claim term, the accused infringer again attempted to limit the scope of the patent to exclude warning systems that used distance from the airport as a parameter by arguing that a claim term, "ground proximity warning system," had to be limited to FAA-approved warning systems in existence when the inventor filed his patent application. According to the accused infringer, because none of those FAA-approved systems used distance from the airport as a parameter, the patent could not be broadly construed to cover such systems. Rejecting this argument, the Federal Circuit found that specification used the term "ground proximity warning system" in a generic sense and had not limited it to any specific type of system, therefore the district court properly declined to narrowly construe the patent as the accused infringer had urged. *Id.* at *7.

For a patent directed to a computer-assisted system for administering CPR, the Federal Circuit, in *Hutchins v. Zoll Med. Corp.*, No. 2006-1539, 2007 WL 1892467, *2-*3 (Fed. Cir. July 3, 2007), affirmed a district court's construction of a claim limitation reciting a "general purpose computer" as excluding from its scope a dedicated microprocessor. During prosecution the inventor added the limitation of a "general purpose computer" to distinguish over prior art having dedicated microprocessors. By doing so the inventor created a classic estoppel, which precluded the claim from covering dedicated microprocessors. Since the accused product only used a dedicated microprocessor, the district court properly granted summary judgment of noninfringement. *Id.* at *2. The Federal Circuit further found that a second claim limitation requiring an "interactive display input" was not met by the accused product because the proper construction of the term required an input device that the human operator could use to interactively input data to the system. In the accused product, sensors were used to monitor a victim's vital signs, which signals were fed directly into the accused device. The human operator never inputted any data interactively to the system, and the system did not permit the operator to do so. Hence, for this additional reason, the court concluded that no reasonable jury could find infringement. *Id.* at *3.

Addressing the binding effect of claim constructions made in prior litigation involving the asserted patent, a district court held in *Amgen, Inc. v. F. Hoffmann-La Roche Ltd.*, 2007 WL 1893058, *3-*4 (D. Mass. July 3, 2007), that issue preclusion would bind a patentee to claim constructions rendered by the district court in a prior case since the patentee was a participant in that prior case and all four conditions for applying issue preclusion were met. The court further held that because the accused infringer had not participated in the prior suit, issue preclusion would not apply to bind the accused infringer to the district court's prior claim constructions. The court further held, however, that fairness required applying the prior claim constructions to the current suit unless the accused infringer came forward with arguments sufficient to cause the court to alter its prior construction. As to claim constructions rendered, adopted, or affirmed by the Federal Circuit in the appeal of the prior case, the district court held that under the principles of *stare decisis*, both the patentee and accused infringer were bound to the constructions rendered by the Federal Circuit. The court stating that "[w]here the Federal Circuit has already construed the claims here disputed, then that higher Court's construction is binding, and this Court cannot modify its holding."

Obviousness

In another case illustrating that "reasonable expectation success" may be the new post-*KSR* battle ground for obviousness determinations, the Federal Circuit, in *PharmaStem Therapeutics, Inc. v. ViaCell, Inc.*, No. 05-1490,-1551, 2007 WL 1964863, *15-*22 (Fed. Cir. July 9, 2007) (Bryson, Newman and Prost), ordered a district court to enter a judgment that claims directed to a cryopreserved composition of fetal stem cells obtained from a blood in an umbilical cord and a method for preserving, thawing, and using the stem cells in therapy for adults were invalid for being obvious in view of references considered by the PTO. The Federal Circuit found that each step of the cryopreservation and transplantation procedure had been disclosed in the prior art, that there was "a reason to attempt to make the composition and method" based

on suggestions in the prior art, and that no novelty was shown in the method by which the inventor proposed to collect, cryopreserve, and transplant the cord blood. The patentee had argued that the prior art did not teach that the cells from cord blood would yield a suitable stem cell for therapy for adults, and therefore there was no reasonable expectation of success that the claimed composition could be achieved or that the claimed method would work. To support this argument, the patentee proffered expert testimony that the prior art only noted the possibility that cord blood might contain suitable stem cells. But the Federal Circuit ruled that the inventor's statements in the specification characterizing the prior art as teaching that suitable stem cells existed in umbilical cord blood, even if not wholly accurate, defeated any reliance by the patentee or PTO on the argument that the prior art failed to disclose that cord blood had suitable stem cells; the only alleged novel aspect of the claimed invention. Ruling that due to the admission in the specification the jury was legally obligated to assume that suitable stem cells were in cord blood, the Federal Circuit concluded that the claimed invention only showed a scientific confirmation of what was known in the prior art, and did so only by applying routine scientific methods. Writing for the panel, Judge Bryson instructed: "While the inventors may have proved conclusively what was strongly suspected before—that umbilical cord blood is capable of hematopoietic reconstitution—and while their work may have significantly advanced the state of the science of hematopoietic transplantations by eliminating any doubt as to the presence of stem cells in cord blood, the mouse experiments and the conclusions drawn from them were not inventive in nature. Instead, the inventors merely used routine research methods to prove what was already believed to be the case. Scientific confirmation of what was already believed to be true may be a valuable contribution, but it does not give rise to a patentable invention." *Id.* at 19.

Judge Newman dissented. In her view, the fact that the patents withstood three reexamination proceedings, that the patentee created an entire industry around the patented technology, that there was a long-felt need for the claimed invention, and that the inventions received widespread acclaim in the scientific community provided powerful evidence of non-obviousness. She criticized the panel's apparent limiting of patentable subject matter to the unexpected by stating: "[m]y colleagues go too far in limiting the patent system to the serendipitous and the unexpected." *Id*. at 34.

In a second case concerning obviousness, the Federal Circuit reversed a finding that claims to a method of treating an ear infection by topically administering the antibiotic olfaxacin into the ear were not invalid in view of a prior-art reference disclosing the use of ciprofloxacin, an antibiotic in the same family as olfaxacin, as being safe and effective for treating ear infections. *Daiichi Sankyo Co. Ltd. v. Apotex, Inc.*, No. 2006-1564 (Fed. Cir. July 11, 2007) (*nonprecedential*). This case did not focus on the application of *KSR*. Instead, the case turned on the proper determination of the level of skill in the art. Relying on dicta in a prior Federal Circuit opinion, the district court ruled that the level of skill of in the art was that of a general medical practitioner who would prescribe the treatment method. Based on this level of skill, the district court found that one of skill would not appreciate that the prior-art reference disclosing the use of ciprofloxacin to treat ear infections had application to using olfaxacin to treat ear infections. The Federal Circuit rejected the finding that the level of skill was that of a general medical practitioner. It noted that the named inventors and others in the field were "specialists in drug and ear treatments—not general practitioners or pediatricians," and that the nature of the problem to be solved involved drug formulation and animal testing, subject matter outside the scope of expertise of a general practitioner. Accordingly, the Federal Circuit agreed with the accused infringer that the proper level of skill in the art was "a person engaged in developing pharmaceutical formulations and treatment methods for the ear or a specialist in ear treatments." *Slip opn* at 4-5. In view of this more sophisticated level of skill, the Federal Circuit concluded that one of ordinary skill would have a reasonable expectation of success in using olfaxacin to treat ear infections without adverse side effects given the prior-art disclosure that ciprofloxacin achieved these results, that olfaxacin was in the same family as ciprofloxacin, and both chemicals were gyrase inhibitors. Further, the court noted that the patentee did not introduce any evidence to counter the expert testimony from the accused infringer that one of skill in the art would have had a reasonable expectation of success in using olfaxacin based on the disclosure of ciprofloxacin. The court concluded, therefore, that as a matter of law the claims were invalid for being obvious in view of the prior art. *Slip opn* at 6-8.

Contributory Infringement

In a second aspect to the Federal Circuit's opinion in *PharmaStem Therapeutics, supra*, the court held that contributory infringement under § 271(c) requires a sale or an offer to sell a *product* constituting a material component of a patented invention. (The court did not address importing a product, which is a third alternative listed in § 271(c)). Affirming a JMOL overturning a jury verdict of infringement, the Federal Circuit held that the sale of *services* performed on a product owned by another did not meet § 271(c)'s requirement of a "sale." The court held that "[u]nder the plain language of the statute, a person who provides a service that assists another in committing patent infringement may be subject to liability under section 271(b) for active inducement of infringement, but not under section 271(c) for contributory infringement." 2007 WL 1964863, at *13. In the case, the accused infringers sold a service to customers of collecting and storing blood from an umbilical cord and returning the blood to the customer at a later time for developing stem cells for transplanting. Since the accused infringers had to return to the customer the same blood it stored for the customer, the court held that the accused infringers were bailees and the transaction did not amount to a sale of the blood. *Id.* at *12.

Declaratory Judgments

A district court held in *Prasco, LLC v. Medicis Pharmaceutical Corp.*, 2007 WL 1974951, *3 (S.D. Ohio July 3, 2007), that no case or controversy sufficient to support subject-matter jurisdiction of a patent-related declaratory judgment action existed where a patentee had not initiated any licensing negotiations with the plaintiff and had not made any statements that the plaintiff's product infringed. The plaintiff argued that the patentee's marking its products with its patent number created the circumstances to support jurisdiction analogous to the scenario in *Teva Pharmaceuticals USA, Inc. v. Novartis Pharmaceuticals Corp.*, 482 F.3d 1330 (Fed. Cir. 2007), where the patentee had listed is drug patent on the FDA Orange Book and had sued the infringer on other ANDAs for other patents related to the same accused drug product. The court rejected this agreement. Noting that even if complying with the marking statute could be equated with listing a patent on the Orange Book, the court found that the circumstances in *Teva* were significantly different from the case before it. *Id.* The district court further found that the prior history of litigation between the parties did not show a case or controversy since the prior litigation involved different products, technology, and patents, and therefore it failed to provide probative evidence demonstrating the possibility of future litigation by the patentee. *Id.* Finally, the district court rejected the argument that the patentee's refusal to give the plaintiff a covenant-not-to-sue showed a sufficient controversy under the circumstance because the plaintiff could not point to any statements by the patentee accusing the plaintiff of infringing the challenged patent. *Id.*

In a case denying a motion to dismiss for lack of a case or controversy, a district court acknowledged that *Medimmune* and its progeny have effectively "lower[ed] the bar for a plaintiff to bring a declaratory judgment action in a patent dispute," the district court in *Frederick Goldman, Inc. v. West*, 2007 WL 1989291, *3 (S.D.N.Y. July 6, 2007). The court further held that a patentee's sending letters and e-mails to customers of the plaintiff, which provided "notice of potential patent infringement" and contained a statement that the patentee intended to pursue its rights against the customer's supplier, easily showed that a substantial controversy existed.

LEGISLATIVE HAPPENINGS

On July 12, 2007, the Senate Judiciary Committee marked-up the proposed Senate bill S. 1145 on patent reform. The committee's working draft retains the controversial provisions regarding apportionment of damages and permitting interlocutory appeals of claim-construction rulings. The committee amended the bill's provisions addressing venue for patent actions to further restrict where patentees may sue accused infringers and to permit certain classes of plaintiffs, e.g., micro-entities and educational based entities, to sue in their home forums. The committee also added an amendment to modify § 287(a) to require patentees to give actual notice to an accused infringer of the patent and an infringement charge for patents that do *not* fall within the duty to mark. For these patents, the damage period would be limited to infringing acts done up to two years before the patentee gave actual notice or, if no notice is given, two years before the filing of the complaint. The maximum period for which damages could be sought would limited to six years before the filing of the complaint.

ADMINISTRATIVE HAPPENINGS

On July 9, 2007, the Office of Management and Budget (OMB), through the Office of Information and

Regulatory Affairs (OIRA), approved the proposed USPTO rule changes concerning new limits on the filing of continuation applications and new limits on the number of claims that may be examined in an application. According to Executive Order 12866 (1993), the USPTO is free to publish these rules as final, since the OIRA appears to have "completed its review without any requests for further consideration." 58 Fed. Reg. 51735 at 51743-44.

The new rules are designed for the USPTO to meet its productivity goals by decreasing the number of potential applications the Office must examine, as well as by reducing the number of claims that must be examined in each application. Although the substance of the Final Rules will not be known until the rules are published in the Federal Register, the new rules may no longer let unlimited claiming and the filing of continuation applications be a matter of right. For example, the new continuation rules could require that second or subsequent continuation applications and second or subsequent RCEs include a showing as to why the amendment, argument, or evidence presented was not previously submitted. Under the new claim limiting rules, the USPTO may limit examination only to independent claims and any dependent claims the applicant expressly elects for separate examination. Additionally, for applications having more than ten independent claims, the USPTO may require a patentability report directed to all independent claims in that application. The USPTO may also require a patentability report of all claims elected for examination if the number of independent claims plus the number of dependent claims so elected exceeds ten. It is not clear whether the new rules will apply retroactively to pending applications.

At this point in the rule-making/review process, all that remains is for the USPTO to publish the rules as final rules. The Final Rules will then become effective 30 days after publication in the Federal Register. Thus, we should expect the new rules to be implemented this year and as early as August or September.